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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,589	01/15/2004	Keizo Koya	3211.1001-001	5403

21005 7590 09/22/2006

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EXAMINER

ANDERSON, JAMES D

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,589

Applicant(s)

KOYA ET AL.

Examiner

James D. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-11 and 13-35 is/are rejected.
- 7) ☒ Claim(s) 3,4 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1 sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 3/06/2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1-35 are currently pending and are the subject of this Office Action. Claims 1, 12, 17, 18, 22, 24, 25 and 29 are presently amended.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-29 and 35 are again rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 78-117 of U.S. Patent No. 6,800,660 and claims 85-125 of U.S. Patent No. 6,762,204. The rejection is maintained essentially for the reasons set forth in the Office Action mailed on 11/03/2005. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims do not preclude the administration of taxol in the method described therein.

Applicants argue that the instant claims are directed to the treatment of cancers comprising the administration of the compound represented by the formula recited in claim 18 alone or in combination with a second anti-cancer agent other than a taxol analog. Applicant's arguments have been considered but they are not persuasive. Claim 18, and claims dependent from claim 18, does not preclude the administration of the compound recited therein in combination with taxol itself, only analogs of taxol. Specifically, claim 18 recites, "...wherein the subject is optionally co-administered a second anti-cancer agent other than a taxol analog or an analog of a taxol analog." As such, the instant claims encompass administration of taxol itself as claimed in the '660 and '204 patents.

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Claims 18-19, 24 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 16-20 and 24 of U.S. Patent No. 7,001,923. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims do not preclude the administration of taxol in the method described therein. As such, claim 18-19, 24 and 35 of the instant application are commensurate in scope with claims 11, 16-20 and 24 of the '923 patent.

Claim 18, and claims dependent from claim 18, does not preclude the administration of the compound recited therein in combination with taxol itself, only analogs of taxol. Specifically, claim 18 recites, "...wherein the subject is optionally co-administered a second anti-cancer agent other than a taxol analog or an analog of a taxol analog." As such, the instant claims encompass administration of taxol itself as claimed in the '923 patent.

Claims 18-19, 24-29 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 16-20 and 24 of U.S. Patent No. 7,037,940. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims do not preclude the administration of taxol in the method described therein. As such, claim 18-19, 24-29 and 35 of the instant application are commensurate in scope with claims 11, 16-20 and 24 of the '940 patent.

Claim 18, and claims dependent from claim 18, does not preclude the administration of the compound recited therein in combination with taxol itself, only analogs of taxol. Specifically, claim 18 recites, "...wherein the subject is optionally co-administered a second anti-cancer agent other than a taxol analog or an analog of a taxol analog." As such, the instant

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claims encompass administration of taxol itself in combination with the recited compounds as claimed in the '940 patent.

Claims 1-2, 5-11, 13-19, 22-28 and 30-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-29 of copending Application No. 11/157,213. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds recited in the claims of the '213 application encompass the compounds of the instant claims when the instant compounds are "a pharmaceutically acceptable salt thereof". The salts recited in the '213 application are resonance forms of the instantly claimed compounds. As such, the instant claims and the claims of the '213 application are commensurate in scope when a salt of the instant compounds is administered to treat cancer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 3-4 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Claims 1-2, 5-11 and 13-35 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038.

The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



James D. Anderson
Patent Examiner
AU 1614

August 18, 2006



ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER